

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

|                                                                                                                                  |                                                                                       |                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Applicant's or agent's file reference<br>101216-1 WO                                                                             | <b>FOR FURTHER ACTION</b>                                                             | See item 4 below                                                          |
| International application No.<br>PCT/SE2004/001258                                                                               | International filing date ( <i>day/month/year</i> )<br>01 September 2004 (01.09.2004) | Priority date ( <i>day/month/year</i> )<br>04 September 2003 (04.09.2003) |
| International Patent Classification (8th edition unless older edition indicated)<br>See relevant information in Form PCT/ISA/237 |                                                                                       |                                                                           |
| Applicant<br>ASTRAZENECA AB                                                                                                      |                                                                                       |                                                                           |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |                                                                                                                                                                 |
|-------------------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report                                                                                                                                             |
| <input type="checkbox"/>            | Box No. II   | Priority                                                                                                                                                        |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability                                                                |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention                                                                                                                                      |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited                                                                                                                                         |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application                                                                                                                |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application                                                                                                           |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

|                                                                                                                                     |                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland<br><br>Facsimile No. +41 22 740 14 35 | Date of issuance of this report<br>06 March 2006 (06.03.2006)<br><br>Authorized officer<br><br><div style="text-align: center; font-weight: bold; font-size: 1.2em;">Philippe Becamel</div><br><br>Telephone No. +41 22 338 70 90 |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 10 JAN 2005

WIPO

PCT

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

ASTRAZENECA  
Global Intellectual Property  
151 85 Södertälje

Date of mailing  
(day/month/year)

05 -01- 2005

Applicant's or agent's file reference

101216-1 WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/SE2004/001258

International filing date (day/month/year)

01.09.2004

Priority date (day/month/year)

04.09.2003

International Patent Classification (IPC) or both national classification and IPC

C07D 401/12, A61K 31/4439, C07C 211/38, A61P 1/04

Applicant

AstraZeneca AB et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further opinions, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/SE  
Patent- och registreringsverket  
Box 5055  
S-102 42 STOCKHOLM

Facsimile No. +46 8 667 72 88

Authorized officer

Per Renström/BS

Telephone No. +46 8 782 25 00

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
**PCT/SE2004/001258**

**Box No. I      Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language, \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/SE2004/001258

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1 4

because:

☒ the said international application, or the said claims Nos. 1 4  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See PCT Rule 67.1.(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ The claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of  
the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not  
comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/SE2004/001258

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

|                               |        |      |     |
|-------------------------------|--------|------|-----|
| Novelty (N)                   | Claims | 1-13 | YES |
|                               | Claims | -    | NO  |
| Inventive step (IS)           | Claims | 1-13 | YES |
|                               | Claims | -    | NO  |
| Industrial applicability (IA) | Claims | 1-13 | YES |
|                               | Claims | -    | NO  |

2. Citations and explanations:

Documents cited in the International Search Report:

D1: EP0124495

D2: WO9427988

The cited documents, representing the general state of the art, do not disclose the invention defined in claims 1-13 or give any indication that would lead a person skilled in the art to it. Accordingly, the invention defined in claims 1-13 is novel and is considered to involve an inventive step. The invention is industrially applicable.

# PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

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| Applicant<br>ASTRAZENECA AB                                                                                                      |                                                                                       |                                                                           |

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| <input type="checkbox"/> Box No. IV             | Lack of unity of invention                                                                                                                                      |
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|                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                      |                                                               |                                            |                                |
|-------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------------------------------|--------------------------------|
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland<br><br>Facsimile No. +41 22 740 14 35 | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Date of issuance of this report<br/>06 March 2006 (06.03.2006)</td> </tr> <tr> <td style="padding: 2px;">Authorized officer<br/><br/>Philippe Becamel</td> </tr> <tr> <td style="padding: 2px;">Telephone No. +41 22 338 70 90</td> </tr> </table> | Date of issuance of this report<br>06 March 2006 (06.03.2006) | Authorized officer<br><br>Philippe Becamel | Telephone No. +41 22 338 70 90 |
| Date of issuance of this report<br>06 March 2006 (06.03.2006)                                                                       |                                                                                                                                                                                                                                                                                                                                                      |                                                               |                                            |                                |
| Authorized officer<br><br>Philippe Becamel                                                                                          |                                                                                                                                                                                                                                                                                                                                                      |                                                               |                                            |                                |
| Telephone No. +41 22 338 70 90                                                                                                      |                                                                                                                                                                                                                                                                                                                                                      |                                                               |                                            |                                |

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INTERNATIONAL SEARCHING AUTHORITY

REC'D 10 JAN 2005

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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

ASTRAZENECA  
Global Intellectual Property  
151 85 Södertälje

Date of mailing  
(day/month/year) **05 -01- 2005**

Applicant's or agent's file reference  
101216-1 WO

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/SE2004/001258

International filing date (day/month/year)  
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/SE2004/001258

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

|                               |        |      |     |
|-------------------------------|--------|------|-----|
| Novelty (N)                   | Claims | 1-13 | YES |
|                               | Claims | -    | NO  |
| Inventive step (IS)           | Claims | 1-13 | YES |
|                               | Claims | -    | NO  |
| Industrial applicability (IA) | Claims | 1-13 | YES |
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2. Citations and explanations:

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